

differentiates between tablets suitable for swallowing whole and the chewable tablets that are the subject of the Bolt patent:

Solid dosage forms which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems; but since they have to disintegrate in the gastrointestinal tract and the medicament has then to dissolve before it can be absorbed, absorption tends to be slower than from a suspension, and may be less than complete. Also, some patients have difficulty swallowing tablets and capsules, and there is a practical limit to the size, and therefore the dose, that can be swallowed.

In general, chewable tablets are advantageous in that they combine the accuracy of dosage associated with tablets [i.e., tablets that are swallowed], with the optimum bioavailability of suspensions. They may also accommodate larger doses than swallow tablets or capsules.

See page 2, lines 9-13 and 19-21.

Bolt describes two kinds of tablets: chewable tablets (that are the subject of Bolt's invention) and tablets that may be swallowed whole. Bolt clearly did not intend for the chewable tablets to be swallowed whole, and offers no teaching to support a suggestion that the chewable tablets even *could be* swallowed whole. The Office has not offered any evidence, other than the Examiner's opinion, to show that Bolt's chewable tablets may be swallowed whole. Respectfully, Applicants assert that the Office ignores the express teachings of Bolt -- which, as Applicants have previously stated, teaches *away from* a suggestion that Bolt's compositions may be swallowed whole.

The Office asserts that "since taste problems are associated with chewable tablets, it is obvious to one of ordinary skill in the art to have swallowed the tablet." Applicants respectfully disagree. Bolt describes in great detail how taste problems -- if present -- may be avoided in the chewable dosage forms described therein. Bolt gives not a single example of a composition according to their invention that is adapted for swallowing without prior disintegration and instead, every example they give is for either a chewable tablet or one that may be dispersed in water before oral administration. One of skill in the art provided with the teachings of Bolt et al. would **not** have been

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motivated to prepare a non-chewable tablet or other dosage form. Bolt repeatedly remarks on the reasons why their chewable or dispersible formulations are preferred over dosage forms that are swallowed, as previously noted. Bolt goes on to mention the taste problems that may be present with chewable tablets, but then report that their invention is one way to solve the problem:

[The acceptability of chewable tablets] is, however, reduced for bitter tasting medicaments, such as antibiotics, especially at higher doses, for example 500 mg and above. ... It has now been found that the inclusion of an effervescent couple in chewable tablets of bitter-tasting medicaments has surprising advantages with respect to palatability, in addition to assisting the break-up of the tablets in the mouth when chewed or sucked.

Nothing in Bolt would have led one of skill in the art to prepare the claimed compositions adapted for swallowing without prior disintegration. The teachings of Bolt, taken as a whole, clearly teach away from such compositions. Nothing in Harrison would lead one of skill in the art back to the claimed compositions, and thus the invention as defined by claims 18, 20, 21, 23-37, and 39-53 is patentable over Bolt in view of Harrison.

The Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,



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Via EFS